



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------------|
| 10/575,500 | 04/11/2006 | Xing Zhou | SCI1.PAU.01.US | 3932 |
| 23386 | 7590 | 09/01/2009 | | |
| Myers Andras Sherman LLP 19900 MacArthur Blvd. Suite 1150 Irvine, CA 92612 | | | EXAMINER EASTWOOD, DAVID C | |
| | | | ART UNIT 3731 | PAPER NUMBER |
| | | | MAIL DATE 09/01/2009 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/575,500 | Applicant(s) ZHOU ET AL. | |
| | Examiner DAVID EASTWOOD | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/2009 has been entered.

Response to Amendment

Receipt is acknowledged of applicant's amendment filed 8/10/2009. Claim 12 has been cancelled without prejudice. Claims 1-11 and 13-20 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7-8, 15 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Specter (US 5135222).

Art Unit: 3731

Regarding Claims 1, 7-8, 15, and 19, Spector discloses an easily retrieved biological specimen pouch comprising a flexible wall (10a), an open end and a closed end (Figure 1, top and bottom of bag), and said specimen pouch can receive the biological specimen therein; said flexible wall of the open end of the specimen pouch has discontinuous serration (N); on said serration, there are slots (12,13) through which string can pass, wherein the string opens and closes the specimen pouch (Figure 1), wherein one end of the said string (14a,b) is connected with a slipknot or slip block (16), a noose structure (loop of string 14) is formed when the other end passes through the slots in the serration of the open end in the specimen pouch and then the slipknot or slip block (16), wherein the pouch deployment and retrieval string opens and closes the specimen retrieval pouch (Column 4 lines 51-60), said flexible wall of the specimen pouch is made of the soft macromolecule materials or compound materials which are enhanced by synthetic fiber (Column 4 lines 18-21).

With regard to claim 1, and the limitation “wherein said slots are shaped in the open end of the specimen pouch by a thermoplastic jointing of the flexible wall, and then the flexible wall of the open end is cut into said discontinuous serration.” It is noted that the device of Spector appears to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Art Unit: 3731

3. Claims 1, 7-11, 13, 15 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Conlon et al (US 6409733).

Regarding Claim 1, 7-11, 13, 15 and 19 , Conlon et al discloses an easily retrieved biological specimen pouch comprising a flexible wall (79), an open end (76) and a closed end (77), and said specimen pouch can receive the biological specimen therein; said flexible wall of the open end of the specimen pouch has discontinuous serration (85,86); on said serration, there are slots (85,86) through which a string can pass, wherein the string opens and closes the specimen pouch (Figure 8), wherein one end of the said string (95) is connected with a slipknot or slip block (97), a noose structure (loop of string 95 surrounding bag 79) is formed when the other end passes through the slots in the serration of the open end in the specimen pouch and then the slipknot or slip block (97), wherein said flexible wall (79) of the specimen pouch is made of the soft macromolecule materials or compound materials, wherein said flexible wall (79) of the specimen, pouch is made of the soft macromolecule materials or compound materials which are enhanced by metal net or synthetic fiber, wherein said flexible wall (79) of the specimen pouch is made of the soft macromolecule materials or compound materials which are enhanced by memory alloy fiber net or synthetic fiber net, wherein said soft macromolecule materials are selected from the following elastomer or polymer materials: Silicon Rubber, Polyurethane, Polyethylene, Polypropylene, Silicone, Ethenoid Resin and Polytetrafluoroethylene (Column 6 lines 15-24), wherein said string (95) is Connected to a distant end of an inner sheath (26), and the specimen pouch (75) is installed in front of the distant end of the inner sheath and inside a distant end of an

Art Unit: 3731

outer sheath (Figures 1 and 2), wherein said the relative position of the outer sheath (25) and inner sheath (26) is fixed by the orientation button (56).

With regard to claim 1, and the limitation “wherein said slots are shaped in the open end of the specimen pouch by a thermoplastic jointing of the flexible wall, and then the flexible wall of the open end is cut into said discontinuous serration.” It is noted that the device of Conlon et al. appears to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2-5, 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Specter (US 5135222) in view of Avellanet (US 6278057) further in view of Cope et al (US 5064428).

Regarding Claims 2-5 and 16-17 and 20, Specter discloses the claimed invention except for said string is made of any materials which can save the changed shape and return to the original or near the original shape when disentangled, said string said string is an open spring made of any materials which can save the changed shape and return to the original or near the original shape when disentangled, said string/open spring is made of the following materials: shape memory alloy wires or pieces or alloy spring steel, wherein the pouch deployment and retrieval string returns to an open state based on temperature of a body.

However, Avellanet discloses nickel titanium alloy (nitinol) wires/strings for use with snares and surgical baskets (Column 4 example 1 and column 5 example 2) and are naturally trained to form a desired size in vivo (Column 5 lines 50-52), Cope et al teaches that nitinol is transformable from a deformed state to a predetermined trained shape once heated to it's operable range (Column 2 lines 47-65). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the nitinol string as taught by Avellanet. Doing so would provide a support structure for the entire circumference of the opening of the bag once deployed in vivo.

Regarding Claim 18, the invention of Specter as modified by Avellanet discloses the claimed invention except for wherein the temperature is in the range of 15°C-33°C.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to set the shape memory alloy transformation temperature to the range of 15-33°C, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

7. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlon et al. (US 6409733) in view of Avellanet (US 6278057).

Regarding claims 4-6, Conlon discloses the claimed invention except for said string is an open spring made of any materials which can save the changed shape and return to the original or near the original shape when disentangled, wherein said open spring is made of the following materials: wires of macromolecule materials, compound materials or metal materials, shape memory alloy wires, shape memory alloy pieces and alloy spring steel. However, Avellanet discloses nickel titanium alloy (nitinol) wires/strings for use with snares and surgical baskets (Column 4 example 1 and column 5 example 2) and are naturally trained to form a desired size in vivo (Column 5 lines 50-52). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Conlon with the shape memory alloy string as disclosed by Avellanet. Doing so would provide a means for further supporting the rim of the basket while deployed in vivo.

8. Claims 9-11 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Specter (US 5135222) in view of Conlon et al (US 6409733).

Art Unit: 3731

Regarding claim 9-10, Specter discloses the claimed invention except for said flexible wall of the specimen pouch is made of the soft macromolecule materials or compound materials which are enhanced by memory alloy fiber net or synthetic fiber net, said soft macromolecule materials are selected from the following elastomer or polymer materials: Silicon Rubber, Polyurethane, Polyethylene, Polypropylene, Silicone, Ethenoid Resin and Polytetrafluoroethylene.

However, Conlon discloses a multi layered flexible wall basket made of Polyurethane enhanced by a Kevlar mesh/net (Column 6 lines 15-23). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the flexible walled basket with reinforcing net/mesh as taught by Conlon. Doing so would provide a retrieval bag with increased tensile strength along its annular walls.

Regarding Claim 11 and 13, Specter discloses the claimed invention except for said string is connected to a distant end of an inner sheath, and the specimen pouch is installed in front of the distant end of the inner sheath and inside a distant end of an outer sheath, wherein one end of the said string is connected with a slipknot or slip block, a noose structure is formed when the other end passes through the slots in the serration of the open end in the specimen pouch and then the slipknot or slip block, said the relative position of the outer sheath and inner sheath is fixed by the orientation button.

However Conlon discloses a string (95) connected to a distant end of an inner sheath (26) where a specimen pouch (77) is in front of the distal end of an inner sheath

Art Unit: 3731

inside a distal end of an outer sheath (25) where the string forms a slipknot (97) forming a noose structure (Figure 2 and 9) and the position of the inner sheath relative to the outer sheath is fixed by an orientation button(56) (figure 3 and 5) (Column 9 lines 4-7).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the deploying apparatus as taught by Conlon.

Doing so would provide a device for deploying the specimen bag in vivo.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Specter (US 5135222) in view of Matey et al (US 5649021).

Regarding Claim 14, Specter discloses the claimed invention except for said open end of the specimen pouch is colored distinctly from the biological specimen observed under the endoscopic equipment.

However, Matey discloses a laparoscopic tool used in vivo having a unique color marker not found on the interior of the abdomen (Column 3 lines 55-59). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the contrasting color as taught by Matey. Doing so would provide a specimen bag which would be easily identifiable with known endoscopic devices in vivo.

Response to Arguments

Applicant's arguments with respect to claims 1-11 and 13-14 have been considered but are moot in view of the new grounds of rejection.

Applicant's arguments filed 8/10/2009 with regards to claims 15-20 have been fully considered but they are not persuasive. Applicant states that the Specter

Art Unit: 3731

reference is incapable of receiving a biological specimen. The examiner respectfully disagrees; the Specter reference is sized and shaped to receive a ball (11) thus would be sized and shaped to be capable of receiving and holding biological tissue.

Applicant asserts that the noose of Conlon is incapable of opening the retrieval basket. The examiner respectfully disagrees, when the bag is in a closed state, with spring arms (47) applying a biasing force to the rim of the bag, release of tension on string and noose (96) opens the specimen bag.

Applicant states that Conlon does not teach slots or a channel in which a string passes. Again the examiner respectfully disagrees. Conlon teaches a slot or channel through which the noose (96) resides (C7 L19-25).

Applicant states that Cope does not disclose a device which opens upon being exposed to body temperature. The examiner disagrees, Cope discloses that the device is above transformation temperature (open state) when in **OPERATING CONDITION** (C 2 L 61). The examiner is interpreting this operating condition as being **in vivo** at body temperature, approx. 98.6 deg. Fahrenheit, while room temperature is well below this thus capable of being below the transformation temperature. In light of this interpretation Cope discloses a basket which opens upon being exposed to body temperature.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is

Art Unit: 3731

(571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/29/09